AUG 11 2005

510(k) SUMMARY

K051533

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Submitter's name:	CL Médical
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Tel:	00.33.(0)4.78.59.54.93
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Contact person:	Vincent GORIA
Date of summary preparation:	June 1st, 2005
Device common name:	Surgical mesh, Sling, Urethral Sling
Device trade name:	I-STOP
Device classification name:	Surgical mesh, polymeric (21 CFR 878.3300)
Product code:	OTN
Regulatory status:	Class II
Predicate Devices:	- Gynecare TVT System: K012628 - SPARC Sling System: K013355 - MONARC Sling System: K023516 - Gynecare TVT-O System: K033568 - Uretex TO: K041176 - Mentor ARIS TOT: K050148

- **Device description:**
I-STOP is a sterile, single use kit consisting of one sling of knitted monofilament polypropylene, two to four stainless steel needles and two polycarbonate handles. The different shapes of the needles allow all the surgical approaches to position the sling.

- **Indications for Use:**
I-STOP® is intended to be used as a pubo-urethral sling for the treatment of female urinary incontinence.

- **Comparison to predicate devices:**
The fundamental scientific technology of I-STOP is the same compared to the predicate devices. The sling is made of the same raw material and with the same manufacturing process. The needles are designed for the same surgical approaches.

- **Summary of testing:**
Mechanical tests, biocompatibility tests in compliance with ISO 10993 and chemical tests.

- **Summary of clinical tests:**
One multicenter retrospective study on a large population, published on European Urology (January 2005) and one multicenter randomized prospective study with ethical committee approval, presented on March and published soon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Vincent Goria
CEO
CL Medical
28, avenue General de Gaulle
69110 Sainte Foy Les Lyon
FRANCE

SEP 28 2012

Re: K051533
Trade/Device Name: I-STOP
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: June 1, 2005
Received: June 9, 2005

Dear Mr. Goria:

This letter corrects our substantially equivalent letter of August 11, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

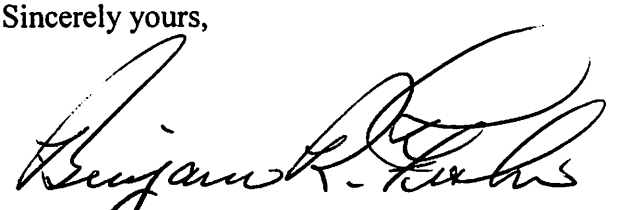
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051533

Indications for Use

510(k) Number (if known): K051533

Device Name: I-STOP

Indications For Use: I-STOP® is intended to be used as a pubo-urethral sling for the treatment of female urinary incontinence.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K051533